

**FIEBRE Standard Operating Procedure F.15d**

<b>Title</b>	Preparation, and shipping of mycobacterial isolates to the reference laboratory		
	<b>SOP Reference</b>	<b>Version</b>	<b>Date of effect</b>
	F.15d	1.1.1	

**SOP Development**

	<b>Name</b>	<b>Title</b>	<b>Signature</b>	<b>Date</b>
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**Review Tracker**

<b>Due date for next review</b>	<b>Reviewer name</b>	<b>Signature</b>	<b>Date reviewed</b>

**Revision History**

<b>Version No.</b>	<b>Effective date</b>	<b>Reason for change</b>

## SOP User Confirmation

I acknowledge that I have read, understood and agree to follow this SOP

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1. **Title: Preparation, and shipping Mycobacterial isolates to the reference laboratory**
2. **Purpose:** To describe the procedures for preparing, and shipping isolates from FIEBRE study sites to the Mycobacterial reference laboratory in Germany.
3. **Responsible staff:** FIEBRE laboratory and co-ordination staff [site-specific]
4. **Background & Rationale:** A Mycobacterial blood culture will be performed for patient's aged 15 and older enrolled in the FIEBRE study at study sites where HIV prevalence in the general adult population is known to be >1%. Laboratory staff at the study site will identify Mycobacteria positive cultures. For external quality control staff will then ship a sample of each isolate to the reference laboratory in Germany, where sub-culture, molecular testing and drug susceptibility testing will be carried out.

This SOP explains the preparation and shipping requirements for transfer from each site directly to the reference laboratory.

### 5. Supplies and Materials

- Sample logbook (paper and ODK)
- A list of isolates to send.

- 2 mL cryovials containing the bacterial isolates, clearly labelled with a barcoded specimen ID and the species name
- Gloves (single-use latex or vinyl)
- Cryogloves for handling dry ice
- Biohazard disposal system
- Lab surface disinfectant (e.g. Biocleanse)
- Box map
- Packaging, shipping labels, and dry ice (to be provided by courier)

## 6. Procedures:

### **6.1 Storage of samples on site (see also FIEBRE SOP F-08a)**

**6.1.1** Mycobacteria isolated from blood should be stored in NaCl with 5% Glycerol or liquid mycobacterial media, as per SOP\_F-08b, in 2 mL cryovials in a -80°C freezer.

### **6.2 Selecting samples for shipment**

**6.2.1** The determination of which samples to ship will be made in discussion with study coordinators and the LSHTM team.

### **6.3 Classification for shipping**

The transportation of Mycobacterial cultures is classified as category A:

**6.3.1 Category A:** an infectious substance which is carried in a form that, when exposure to it occurs, is capable of causing permanent disability, life threatening or fatal disease in otherwise healthy humans or animals. This definition is supplemented by an indicative list of pathogens, which include HIV and hepatitis B viruses (but not hepatitis C virus), when in the form of cultures but does not encompass specimens from patients suspected of having these infections.

## Category A specimens

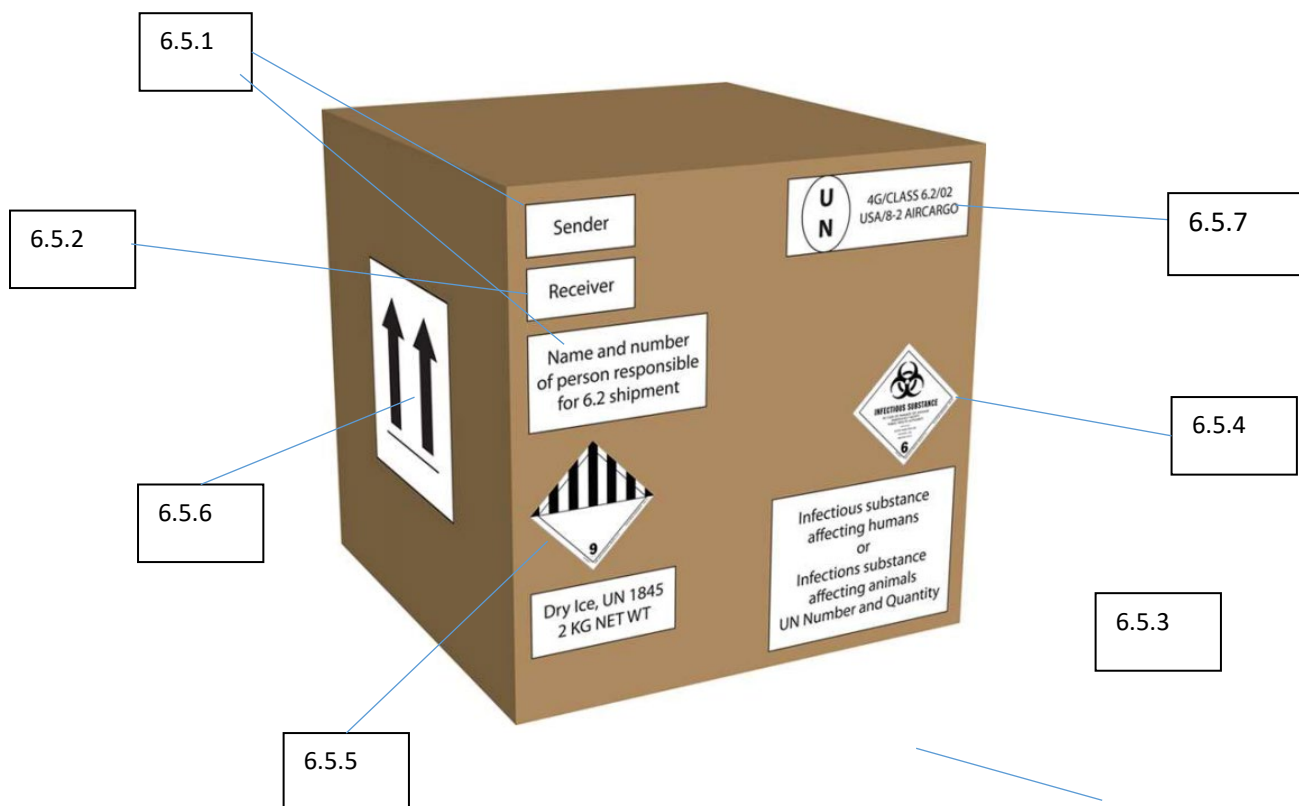
### 6.4 Packaging for Category A packaging

- 6.4.1 Packaging of dry ice samples** –Packaging for Category A infectious substances **must** meet UN performance requirements for Class 6.2 substances as shown by design type testing. These are known as **UN type approved packaging** and they are certified and marked accordingly. Packaging used for Category A infectious substances must be specifically approved for Class 6.2 goods (either primary receptacle or secondary packaging). This can be ensured by purchasing from a specialist company such as AirSea containers, where suitable products are listed under Category A packaging and are appropriately certified and marked (see 6.4.4)
- 6.4.2** All Category A shipments must be triple packaged in accordance with International Air Transport Association (IATA) guidelines.
- 6.4.3** The primary receptacle is the 2 mL leak-proof cryotube holding each sample. These should be securely sealed with waterproof tape.
- 6.4.4** The secondary container must be watertight and leak-proof e.g. Biotubes and Biojar available in various sizes from AirSea containers (airseadg.com) appropriate to volumes being shipped. Several cushioned primary receptacles may be placed in one secondary packaging, but sufficient additional absorbent material must be used to absorb all fluid in case of breakage. Place the sealed primary receptacles within any supplied pouch, wrap in absorbent material and then place them within the secondary container.
- 6.4.5** For air transport the limits per package are as follows: • 50ml or 50g for passenger aircraft • 4L or 4 kg for cargo aircraft. Any primary receptacle with a capacity of more than 50 ml must be oriented in the outer packaging so that the closures are upwards. Orientation labels (“UP” arrows) must be affixed to two opposite sides of the outer packaging.
- 6.4.6** The third layer is a rigid outer box, which will hold the dry ice. The courier will provide these boxes and the dry ice. The boxes should come marked with the appropriate hazard labels (See figure 3)
- Place the secondary packaging within the outer shipping packaging with suitable cushioning material. The outer packaging should bear the United Nations packaging specification marking, which indicates that the packaging has passed the performance tests to the satisfaction of the competent authority

## 6.5 Labelling for Category A outer boxes (see figure 3)

- 6.5.1 Sender's name, address and emergency contact number (your own contact information)
- 6.5.2 Recipient's name, address and emergency contact number (see 6.1)
- 6.5.3 The words "UN 2814 INFECTIOUS SUBSTANCE, AFFECTING HUMANS"
- 6.5.4 Hazard warning label for Class 6.2 - Infectious substances
- 6.5.5 A class 9 label, along with the words "UN1845 Dry ice" and the weight of dry ice in kilograms
- 6.5.6 Packages containing liquids must display "Package Orientation" labels.
- 6.5.7 UN packaging specification mark

Figure 2. Labelling of Category A shipment



## 6.6 Documentation required for Category A shipment

- 6.6.1** Place two copies of each of the following documents in a transparent envelope and affix to the outer box.
- a. A packing list – an itemised list of contents including the number of tubes and their individual volume
  - b. A customs invoice written on site-specific headed paper. Include the number and volume of each sample type shipped. State clearly that these specimens have no commercial value. Contact the LSHTM lab coordinator for a template if needed.
  - c. A certificate of donation on site-specific headed paper. Contact the LSHTM lab coordinator for a template if needed.
  - d. For transport by air complete an Air Waybill and a Shipper's Declaration for Dangerous Goods Contact the LSHTM lab coordinator for a template if needed
  - e. A completed lab request sheet for the receiving lab (see appendix A)

## 6.7 Recipient address for **Mycobacterial isolates**:

Attention of: Florian Maurer/Ms Anne Witt

National and Supranational Reference Centre for Mycobacteria  
Research Centre Borstel  
Leibniz Lung Centre  
Parkallee 18

DE-23845 Borstel

GERMANY

PHONE NUMBER - +49 (0)4537 1882110

## Appendix A – Laboratory request sheets



Formular\_Human\_Sa  
mples\_LSHTM\_solid c



Formular\_Human\_Sa  
mples\_LSHTM\_liquid

**END**